

DESCRIBE AND EVALUATE NUTRIENTS OF PUBLIC HEALTH CONCERN: DATA ANALYSIS PROTOCOL

This document describes the protocol for data analysis to address the following question:
Describe and evaluate nutrients of public health concern.

This data analysis is being conducted by the 2020 Dietary Guidelines Advisory Committee, Data Analysis and Food Pattern Modeling Cross-Cutting Working Group, with support from a federal interagency data analysis team (DAT).

This document includes details about the methodology as it will be applied to the data analysis as follows:

- The [analytic framework](#) (p. 2) describes the overall scope of the question and approach used to describe food group and nutrient intakes
- The [analytic plan](#) (p. 5) details the data and subsequent included analyses
- The [analysis results](#) (p.10) includes reports that describe the analytic methods and summarize results (e.g. data tables and figures)

This protocol is up-to-date as of: 10/22/2019.

This version of the protocol contains the following update.

- The key definitions, analytic framework and analytic plan now include the elements for infants and toddlers.

ANALYTIC FRAMEWORK

The analytic framework describes the overall scope of the analyses, including the population and type of analyses and data sources identified to answer the question. It also includes the definitions of key terms.

Question: Describe and evaluate nutrients of public health concern.

A three pronged approach will be used to determine nutrients of public health concern:

1. Estimate prevalence of inadequate and excessive nutrient intakes by comparing current distribution of nutrient intakes in the U.S. population to [Dietary Reference Intakes published by the National Academies of Sciences](#).

Nutrient intakes from food and beverages alone as well as the additional contribution of nutrient from intakes of dietary supplements.

- For nutrients with an Estimated Average Requirement (EAR), the estimated prevalence of inadequate intakes will be determined using the EAR cut-point method for nutrients with an EAR. Iron in menstruating women will be evaluated with the probability approach.
 - For nutrients with an Adequate Intake (AI), mean nutrient intakes will be compared to the AI to determine the estimated prevalence above the AI.
 - For nutrients with a Tolerable Upper Intake Level (UL) or Chronic Disease Risk Reduction (CDRR) intake, the estimated prevalence of potentially excessive intakes will be determined by examining the percent of the population with intakes above the UL or CDRR.
 - For nutrients with an Acceptable Macronutrient Distribution Range (AMDR), the estimated prevalence of the population with intakes outside of the range will be evaluated.
 - Percent energy contributed from added sugars and saturated fat will be compared to the 2015-2020 *Dietary Guidelines for Americans* recommendations of <10% of total energy from each nutrient.
2. When available, consider biological endpoints or validated surrogate endpoints such as biochemical indices of nutrient status with valid cut-points in addition to dietary intakes of nutrients.
 3. Consider scientific evidence on the relationship between nutrient inadequacy or excess and clinical health consequences (e.g. cardiovascular disease, cancer).
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Population: Nationally representative sample of the U.S. population.

Life stages:

Infants and toddlers (birth to <24 months)

Children and adolescents (ages 2-18 years)

Adults (ages 19-64 years)

Pregnant women (ages 20-44 years) self-reported pregnancy status and/or positive urinary pregnancy test

Lactating women (ages 20-44 years)

Older adults (ages 65 years and older)

*NOTE: Age ranges may vary and will be specified in analytic plan

Demographic subgroups:

- Sex
- Race-ethnicity
- Socioeconomic status i.e. income, education
- Household food security

Data Source:

Biochemical Indicators

National Health and Nutrition Examination Survey (NHANES); cross-sectional, nationally representative biomarkers of nutrient status.

Data years: 2013-2016, exceptions to these data years will be noted.

Nutrient Intakes

What We Eat in America, National Health and Nutrition Examination Survey (WWEIA, NHANES); cross-sectional, nationally representative dietary intake data.

Data years: 2013-2016, exceptions to these data years will be noted.

The most recent cycle of NHANES data collected in 2015-2016 will be the most current data available for consideration by the Committee. Two cycles will be combined (WWEIA, NHANES 2013-2016) to calculate distributions of nutrient intakes and other analyses when noted.

Key definitions:

Dietary Reference Intakes (DRI) – nutrient reference values developed by the National Academies of Sciences, Engineering and Medicine that are specified on the basis of age, sex and life stage and cover more than 40 nutrient substances.

Acceptable Macronutrient Distribution Range (AMDR) – is the range of intake for a particular energy source that is associated with reduced risk of chronic disease while providing intakes of essential nutrients. If an individual consumes in excess of the AMDR, there is a potential of increasing the risk of chronic diseases and/or insufficient intakes of essential nutrients.

Estimated Average Requirement (EAR) – the average daily nutrient intake level estimated to meet the requirements of half of the healthy individuals in a group.

Recommended Dietary Allowance (RDA) – average daily dietary intake level sufficient to meet the nutrient requirements of nearly all (97-98%) healthy individuals in a group.

Adequate Intake (AI) – established when evidence is insufficient to develop an RDA and is set at a level assumed to ensure nutritional adequacy.

Tolerable Upper Intake Level (UL) – maximum daily intake unlikely to cause adverse health effects to almost all individuals in the general population.

Chronic Disease Risk Reduction (CDRR) – lowest level of intake for which there is sufficient strength of evidence to characterize a chronic disease risk reduction.

Nutrients of public health concern – Nutrients that are overconsumed (compared to the DRI UL or CDRR or AMDR or percent of energy recommendations and to biological measures of the nutrient when available) or under consumed (compared to the DRI EAR/AI/AMDR and to biological measures of the nutrient when available), and linked in the scientific literature to adverse health outcomes in the general population or in a subpopulation.

Human milk – Mother’s own milk provided at the breast (i.e., nursing) or expressed and fed fresh or after refrigeration/ freezing; donor milk is not examined in this review

Human milk feeding – Feeding human milk alone or in combination with infant formula and/or complementary foods and beverages (CFB) such as cow’s milk

Exclusive human milk feeding – Feeding human milk alone and not in combination with infant formula and/or CFB such as cow’s milk; inclusive of WHO definitions of “exclusive” and “predominant” breastfeeding, which permit limited quantities of drops or syrups containing vitamins, minerals, or medicines; water and water-based drinks such as sweetened water and teas; fruit juice; oral rehydration salts solution; and ritual fluids

Infant formula – Commercially prepared infant formula meeting FDA and/or Codex Alimentarius international food standards

Mixed feeding – Feeding human milk and infant formula but not CFB such as cow’s milk

Complementary foods and beverages (CFB) – Foods and beverages other than human milk or infant formula (liquids, semisolids, and solids) provided to an infant or young child to provide nutrients and energy

ANALYTIC PLAN

To describe and evaluate nutrients of public health concern in the U.S. population for each life-stage, analysis will quantify intake of nutrients using WWEIA, NHANES dietary recall data and corresponding nutrient values from the USDA Food and Nutrient Database for Dietary Studies and the Dietary Supplement Database. Biochemical indicators of nutrition status will be assessed using laboratory data from NHANES¹.

Infants 6 to less than 12 months of age

Population total usual nutrient intake distributions from infant milk source, food and beverages among U.S. children ages 6<12 months, total and stratified by infant milk source (i.e. human milk and/or infant formula), using WWEIA, NHANES 2007-2016

Population total usual nutrient intake distributions from infant milk source, food and beverages as well as dietary supplements among U.S. children ages 6<12 months, total and stratified by infant milk source (i.e. human milk and/or infant formula), using WWEIA, NHANES 2007-2016

Comparison of total estimated nutrient intakes, with and without dietary supplements to DRIs among U.S. children ages 6<12 months by infant milk source using WWEIA, NHANES 2007-2016

¹ https://wwwn.cdc.gov/nchs/data/nhanes/survey_contents.pdf

Children (1-18 years, exceptions noted)

Usual intake distributions of nutrient intakes from foods and beverage among children ages 1-18 years, by sex using WWEIA, NHANES 2013-2016

Usual intake distributions of nutrient intakes from foods and beverage and dietary supplements among children ages 1-18 years, by sex using WWEIA, NHANES 2013-2016

Prevalence (in percent) of low serum ferritin concentration for children in the U.S. population aged 1–19 years, NHANES, 2013–2016

Prevalence (in percent) of high serum ferritin concentration for children in the U.S. population aged 1–19 years, NHANES, 2013–2016

Prevalence (in percent) of high serum soluble transferrin receptor concentration in the U.S. population of children 1-5 years, females 12–19 years, NHANES 2013-2016

Prevalence (in percent) of low folate (RBC) concentration in the U.S. population of children ages 1 – 18 years, by sex, NHANES 2013-2016

Prevalence (in percent) of low serum folate concentration in the U.S. population of children ages 1 – 18 years, by sex, NHANES 2013-2016

Prevalence (in percent) of low serum copper concentration in the U.S. population of children ages 6 -18 years, NHANES 2013-2016

Prevalence (in percent) of low serum zinc concentration in the U.S. population of children ages 6-18 years, by sex NHANES 2013-2016

Prevalence (in percent) of low vitamin D (serum 25-hydroxyvitamin D) in the U.S. population of children ages 1-18 years, by sex NHANES 2013-2016

Prevalence (in percent) of low serum vitamin A and/or carotenoids in the U.S. population of children ages 6-19 years, NHANES 2005-2006

Prevalence (in percent) of low serum vitamin C in the U.S. population of children ages 6-19 years, NHANES 2003-2006

Prevalence (in percent) of low serum vitamin E in the U.S. population of children ages 6-19 years, NHANES 2005-2006

Prevalence (in percent) of low serum vitamin B12 in the U.S. population of children ages 1-19 years, NHANES 2003-2006

Prevalence (in percent) of low serum vitamin B6 (serum pyridoxal-5'-phosphate) in the U.S. population of children ages 1-19 years, by sex NHANES 2005-2006

Adults (20 years and older, exceptions noted)

Usual intake distributions of nutrient intakes from foods and beverage among adults ages 19 years and older, by sex using WWEIA, NHANES 2013-2016

Usual intake distributions of nutrient intakes from foods and beverage and dietary supplements among adults ages 19 years and older, by sex using WWEIA, NHANES 2013-2016

Prevalence (in percent) of low serum ferritin concentration for women in the U.S. population aged 20–49 years, NHANES 2013-2016

Prevalence (in percent) of high serum ferritin concentration for women in the U.S. population aged 20–49 years, NHANES 2013-2016

Prevalence (in percent) of high serum soluble transferrin receptor concentration for women in the U.S. population aged 20–49 years, NHANES 2013-2016

Prevalence (in percent) of low folate (RBC) concentration in the U.S. population of adults ages 19 years and older, by sex, NHANES 2013-2016

Prevalence (in percent) of low serum folate concentration in the U.S. population of adults ages 19 years and older, by sex, NHANES 2013-2016

Prevalence (in percent) of high unmetabolized folic acid concentrations in the U.S. population of adults ages 19 and older, by sex, NHANES 2011-2012

Prevalence (in percent) of low serum copper concentration in the U.S. population of adults ages 19 years and older, by sex, NHANES 2013-2016

Prevalence (in percent) of low serum zinc concentration in the U.S. population of adults ages 19 years and older, by sex, NHANES 2013-2016

Prevalence (in percent) of low vitamin B12 status in the U.S. population of adults ages 19 years and older, by age and sex, NHANES 2013-2014

Prevalence (in percent) of high methylmalonic acid in the U.S. population of adults ages 19 years and older, by age and sex, NHANES 2013-2014

Prevalence (in percent) of low vitamin D (serum 25-hydroxyvitamin D) status in the U.S. population of adults ages 20-70 years, by sex, NHANES 2013-2014

Prevalence (in percent) of low serum vitamin A and/or carotenoids in the U.S. population of women ages 20-59 years, NHANES 2005-2006

Prevalence (in percent) of low serum vitamin C in the U.S. population of adults ages 20-59 years, by sex, NHANES 2003-2006

Prevalence (in percent) of low serum vitamin E in the U.S. population of adults ages 40-59 years, by sex, NHANES 2005-2006

Prevalence (in percent) of low serum vitamin B6 (serum pyridoxal-5'-phosphate) in the U.S. population of adults ages 20-59 years, by sex, NHANES 2005-2006

Pregnant Women

Usual intake distributions of nutrient intakes from foods and beverage among pregnant women using WWEIA, NHANES 2013-2016

Usual intake distributions of nutrient intakes from foods and beverage and dietary supplements among pregnant women using WWEIA, NHANES 2013-2016

Prevalence (in percent) of low serum ferritin concentration for pregnant women in the U.S. population, NHANES 2013-2016

Prevalence (in percent) of high serum ferritin concentration for pregnant women in the U.S. population aged 20–49 years, NHANES 2013-2016

Prevalence (in percent) of high serum soluble transferrin receptor concentration for pregnant women in the U.S. population, NHANES 2013-2016

Prevalence (in percent) of low folate (RBC) concentration in the U.S. population of pregnant women, NHANES 2013-2016

Prevalence (in percent) of low serum folate concentration in the U.S. population of pregnant women, NHANES 2013-2016

Prevalence (in percent) of high unmetabolized folic acid concentrations in the U.S. population of pregnant women, NHANES 2011-2012

Prevalence (in percent) of low serum copper concentration in the U.S. population of pregnant women, NHANES 2013-2016

Prevalence (in percent) of low serum zinc concentration in the U.S. population of pregnant women, NHANES 2013-2016

Prevalence (in percent) of low vitamin B12 status in the U.S. population of pregnant women, NHANES 2013-2014

Prevalence (in percent) of high methylmalonic acid in the U.S. population of pregnant women, NHANES 2013-2014

Prevalence (in percent) of low vitamin D (serum 25-hydroxyvitamin D) status in the U.S. population of pregnant women, NHANES 2013-2014

Median urinary iodine status among pregnant women in the U.S., NHANES 2013-2016

Lactating Women

Usual intake distributions of nutrient intakes from foods and beverage among lactating women using WWEIA, NHANES 2013-2016

Usual intake distributions of nutrient intakes from foods and beverage and dietary supplements among lactating women using WWEIA, NHANES 2013-2016

Prevalence (in percent) of low serum ferritin concentration for lactating women in the U.S. population, NHANES 2013-2016

Prevalence (in percent) of high serum ferritin concentration for lactating women in the U.S. population aged 20–49 years, NHANES 2013-2016

Prevalence (in percent) of high serum soluble transferrin receptor concentration for lactating women in the U.S. population, NHANES 2013-2016

Prevalence (in percent) of low folate (RBC) concentration in the U.S. population of lactating women, NHANES 2013-2016

Prevalence (in percent) of low serum folate concentration in the U.S. population of lactating women, NHANES 2013-2016

Prevalence (in percent) of low serum copper concentration in the U.S. population of lactating women, NHANES 2013-2016

Prevalence (in percent) of low serum zinc concentration in the U.S. population of lactating women, NHANES 2013-2016

Prevalence (in percent) of low vitamin B12 status in the U.S. population of lactating women, NHANES 2013-2014

Prevalence (in percent) of high methylmalonic acid in the U.S. population of lactating women, NHANES 2013-2014

Prevalence (in percent) of low vitamin D (serum 25-hydroxyvitamin D) status in the U.S. population of lactating women, NHANES 2013-2014

ANALYSIS RESULTS

This protocol will be updated with the links to the methods and results for each analysis used to describe and evaluate food group and nutrient intakes after the analytic plan has been finalized and implemented.